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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/854,671	05/15/2001	Takahiro Ochi	017498-0155	1143
22428	7590	06/10/2004	EXAMINER	
FOLEY AND LARDNER SUITE 500 3000 K STREET NW WASHINGTON, DC 20007			SAUCIER, SANDRA E	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 06/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<p align="center">Office Action Summary</p>	Application No. 09/854,671	Applicant(s) OCHI, TAKAHIRO	
	Examiner Sandra Saucier	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/9/04, 3/9/04.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-10,12-14,16-22,25-29 and 33-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-10,12-14,16-22,25-29 and 33-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 May 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____. | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
6) <input type="checkbox"/> Other: _____. |
|---|--|

DETAILED ACTION

Claims 1, 3-10, 12-14, 16-22, 25-29, 33-43 are pending and are considered on the merits.

Claim Rejections – 35 USC § 112

Claims 1, 3-10, 12-14, 16-22, 25-29, 33-43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

amount of guidance and working examples

The specification discusses the characteristics that the final product should have, but fails to include any working example or description of the production of the article. The components of the slurry are said to be calcium phosphate with a stated diameter and a cross-polymerisable resin. The ratio of resin and calcium phosphate and amounts to be made into a slurry are not given even in general terms. A bubbling step is preferred to form pores in the slurry. However, no parameters for foaming are taught such as the apparatus set up for bubbling, the rate and duration of gas flow, the density of the slurry, rate of stirring, etc., but foaming by application of a gas or by stirring appears to be critical to the final pore diameter (page 17, second full paragraph). No length of time of drying or sintering is given. In fact, the thin description appears to be directed mainly towards desired characteristics of the size and quality of the interconnecting pores of the final article, not the disclosure of the processes for obtaining them.

nature of the invention

The invention is directed towards the manufacture of an article for implantation and the article itself with very particular pore sizes and configurations.

state of the prior art and unpredictability

The state of the art regarding an implantable article with disclosed processes for forming interconnecting pores of controlled sizes appears to be very limited. The cited prior art of US 6,340,648 appears to be the only prior art discussing pore size and interconnectivity. Since the instant application asserts the novelty of the article manufactured and argues that the processes disclosed in the prior art of WO 93/04013 and US 6,340,648 form distinct products from the instant product, a description of the novel process sufficient to allow those of skill in the art to replicate the product is essential. Particular attention is drawn to applicant's arguments filed 4/9/04 where applicant states "In addition to the differences based on the different processing temperatures, a porosity of the porous body, a pore diameter, a degree of communication of the pores are different, *largely depending on how the slurry is stirred and the degree of gas contained therein*. The types of pores are very important features for preferred embodiment of the presently claimed invention." Applicant has not disclosed any parameters for this argued critical element.

breadth of the claims

The claims are directed to all biomembers made of a calcium phosphate material with the specified pore size, porosity and interconnectivity.

Undue experimentation would be required to practice the invention as claimed due to the amount of experimentation necessary because of the limited amount of guidance and limited number of working examples in the specification, the nature of the invention, the state of the prior art, breadth of the claims and the unpredictability of the art.

Claim Rejections – 35 USC § 103

Claims 1, 3–10, 12–14, 16–22, 25–29, 33–43 are/remain rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,340,648 [A] in combination with Chistolini *et al.* [U] or Itokazu *et al.* [V].

Claims 36-43 are/remain rejected under 35 U.S.C. 103(a) as being unpatentable over WO 93/04013 [A2] in combination with Chistolini *et al.* [U] or Itokazu *et al.* [V].

The claims are directed to an article comprising a porous body of sintered calcium phosphate with globular pores with a porosity of 55-8%, a mean pore diameter of 50-800 microns, including a plurality of large pores having at least three communicating pores of not less than 5 micron diameter and at least one of the communicating pores having a diameter of 25 microns, wherein the total of the open areas is not more than 50% of the pore area, and the pores contain various cells and a method of making the article.

The references are relied upon as explained below.

WO 93/04013 discloses a method of making a sintered porous article for replacing a body member comprising hydroxyapatite, see examples III, VIII and page 10, middle paragraph.

US 6,340,648 discloses an implant comprising an inner part and an outer calcium phosphate sintered part with a porosity of 55-90% with a pore diameter of 150 microns or more and interconnecting pores. The article is formed by foaming with a resin and sintering. The article may be impregnated with a drug, see entire patent.

Itokazu *et al.* disclose that porous hydroxyapatite may be loaded with antibiotic or anticancer drugs prior to implantation.

Chistolini *et al.* disclose that porous hydroxyapatite may be loaded with cells prior to implantation.

The addition of cells into the porous implant disclose in WO 93/04013 or US 6,340,648 would have been obvious when taken with Itokazu *et al.* or Chistolini *et al.* who disclose such an addition.

Response to Arguments

Applicant's arguments filed 3/9/04 and 4/9/04 have been fully considered but they are not persuasive.

Applicant argues that claim 36 includes a step of sintering the dried body at about 1100C, while the product of WO 93/04013 is sintered at 1300C or more. Applicant further argues that hydroxyapatite changes form at temperature of 1300C or more and this fundamentally alters the characteristics of the product.

Claim 36 recites "about" 1100C which may permit a sintering temperature of 1300C or above and not mention of any form of apatite is made in the claims.

Applicant merely asserts that a sintering temperature of 1300C materially affects the final form of the article, but provides no evidence of such assertion.

This argument is merely the argument of counsel and is unsupported by evidence or declarations of those skilled in the art. Counsel's arguments cannot take the place of objective evidence. In re Schulze, 145 USPQ 716 (CCPA 1965); In re Cole, 140 USPQ 230 (CCPA 1964); and especially In re Langer, 183 USPQ 288 (CCPA 1974).

Applicant further argues that the slurry of the present invention and that of WO 93/04013 are different. In WO93/04013, the slurry uses a monomer, while the instant invention uses a cross-polymerisable resin polymer.

On page 6, last paragraph of the reference, it is specifically disclosed that polymers are a suitable dispersion agent as well as polymerisable monomers. On page 9, last paragraph, resins may be included in the dispersion as well as polymerisable materials. Under the influence of heat, the polymerisable monomers cross link to form polymers. During the sintering process, the

polymers are “burned out” Whether one begins with a slurry containing polymers or monomers that are subsequently polymerized, and then burned out during firing does not appear to affect the final product in the absence of evidence to the contrary, especially with regard to the generic teaching present in the reference.

Applicant argues that the article of WO93/04013 is not intended for the same use as the instant product. However, the instant claims are not directed to the use of the article, but to the making of the article and the article itself.

The claimed invention must have a structural difference between it and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Applicant argues that the invention of WO93/04013 is characterized by having a critical viscosity of the slurry, while the slurry used in the instant invention does not have a critical viscosity.

First, there is no disclosure in the AS FILED specification as to the ratio of the components of the slurry or even to the exact components themselves. Therefore, applicant's example in the response of 4/9/04 cannot be associated with the specification, and applicant's arguments are therefore, unpersuasive of error in the formulation of the rejection. A slurry that has no disclosed proportions cannot be found to be distinct from the slurry of the prior art. Applicant states “In addition to the differences based on the different processing temperatures, a porosity of the porous body, a pore diameter, a degree of communication of the pores are different, *largely depending on how the slurry is stirred and the degree of gas contained therein*. The types of

pores are very important features for preferred embodiment of the presently claimed invention.”.

Please see the enablement rejection above where this point was made.

Applicant further argues that the porous articles of WO 93/04013, ex. III and VIII made from hydroxyapatite have a mean diameter of about 16–24micrometers. This appears to be true, and the claims with a distinct mean pore diameter are no longer rejected over this reference.

Applicant states that US 6,34,648 does not teach or suggest features of the presently claimed invention such as the larger pores having a plurality of communicating pores to permit free flow of body fluid.

US'648 in example 1 states that the hydroxyapatite sintered porous body has an average pore diameter of 200 micrometers and a average diameter of communicating parts of 70 micrometers. This appears to be within the claim limitations of a mean pore diameter of 50–800 micrometers with a communicating pore diameter of not less than 25 micrometers. While the reference appears to be silent with regard to the presence of a plurality of large pores having a size larger than the mean pore diameter, a mean, by definition is an average, which necessarily must include pores larger than the mean as well as smaller than the mean. A plurality by definition may be satisfied if only two pores are larger than the mean. Since the process used to make the article in US'648 is the same or very similar to the instantly disclosed process, the products are assumed to be the same in the absence of evidence to the contrary, even though all of the characteristics of the product are not disclosed.

The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicant's article differs and, if so, to what extent from the articles discussed in the references. Accordingly, it has been established that the prior art articles, which have the same composition and share the property of being used for the same purpose,

demonstrate a reasonable probability that it is either identical or sufficiently similar that whatever differences exist are not patentably significant. Therefore, the burden of establishing novelty or unobviousness by objective evidence is shifted to applicants.

Merely because a characteristic of an article is not disclosed in a reference does not make the claimed article patentable. The known article possesses inherent characteristics which might not be displayed in the tests used the reference. However, the article disclosed may be the same article as claimed.

One of ordinary skill in the art would have been motivated at the time of invention to make this addition of cells to the porous implant in order to obtain the resulting composition as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. The examiner can normally be reached on Monday, Tuesday, Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Application/Control Number: 09/854,671
Art Unit: 1651

Page 9

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A handwritten signature in black ink, appearing to read 'Sandra Saucier', with a stylized flourish at the end.

Sandra Saucier
Primary Examiner
Art Unit 1651